



Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

(use as many sheets as necessary)

Sheet 1 of 3

Application Number	10/518,525
Filing Date	12/22/2004
First Named Inventor	Hendrika
Group Art Unit	<del>1618</del> 1648
Examiner Name	<del>William P.</del> Humphrey, L
Attorney Docket Number	TIP0016US

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code* (if known)			
		327,742		Uren	10/06/1885	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				
LH		EP	406985	A2	Janssen Pharmaceutica,N.V.	01/09/1991		
		EP	428000	A1	Abbott Laboratories	05/22/1991		
		WO	97/27319	A1	Virologic, Inc.	07/31/1997		
		PCT	97/27332	A1	Innogenetics,N.V.	07/31/1997		
		PCT	97/27480	A1	Virco,N.V.	07/31/1997		
		PCT	99/67428	A2	Innogenetics N.V.	12/29/1999		
		PCT	00/73511	A1	Virco NV	12/07/2000		
		PCT	00/78994	A1	The Penn State Research Foundation	12/28/2000		
		PCT	00/78996	A1	Virologic, Inc.	12/28/2000		
		WO	01/79540	A2	Virco, N.V.	10/25/2001		
		PCT	01/81624	A1	Virco N.V.	11/01/2001		
		PCT	01/95230	A2	Virco UK Limited	12/13/2001		
		PCT	02/083657	A2	Tibotec Pharmaceuticals Ltd.	10/24/20002		
		PCT	02/22076	A2	Virologic, Inc.	03/21/2002		
		PCT	02/33402	A2	Virco N.V.	04/25/2002		
		PCT	02/38792	A2	Biolliance Pharma	05/16/2002		
		PCT	04/022523	A2	Elan Pharmaceuticals, Inc.	03/18/2004		
Examiner Signature	/Louise Humphrey/				Date Considered	01/23/2007		

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant; Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450**

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 3

Application Number	10/518,525
Filing Date	12/22/2004
First Named Inventor	Hendrika
Group Art Unit	<del>1019</del> 1648
Examiner Name	Whitney P. Humphrey, L
Attorney Docket Number	TIP0016US

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
LH		ABSTRACT: International Congress on Drug Therapy in HIV Infection, Volume 12, Supplement 4, AIDS.online.com	
		ABSTRACT: Comprehensive HIV Drug Resistance Monitoring Using Rapid, High-Throughput Phenotypic and Geotypic Assays with Correlative Data Analysis. Poster Abstracts, OP3.4	
		Condra, Jon ., et al. Genetic Correlates of InVlvo Viral Resistance to Idvavir,a HumanImmunodeficiency Virus Thpe 1 Protease Inhibitor. Journal of Virology, December 1996, pp. 8270-8276	
		<b>GUIDANCE FOR INDUSTRY.</b> U.S. Department of Health and Human Services, Food and Drug Administration	
		Eastman, P. Scott, et al. Nonisotopic Hybridization Asay for Determinatin of Relative Amounts of Genotypic Human Immunodeficiency Virus Tpe 1 Zidovudine Resistance. Journal of Clinical Microbiology, Oct. 1995, pp. 2777-2780	
		Eriksson, Bertil F.H., et al. Phosphorylation of 3'-Azido-2',3'-Dideoxyuridine and Preferential Inhibition of Human and Simian Immunodeficiency Virus Reverse Transcriptases by Its 5'-Triphosphate. Antimicrobial Agents ad Chemotherapy, Oct 1989, pp. 1729-1734	
		Fodor, Stephen P.A., et al. Multiplexed Biochemical Assays With Biological Chips. Nature, August 5, 1993, Vol. 364, pp. 555-556	
		Harada, Shinji, et al. Infection of HTLV-III/LAV in HTLV-I-Carring Cells MT-2 and MT-4 and Application in a Plaque Assay. Department o Virology and Prasitology, Yamaguchi University, Japan, august 9, 1985, p. 563-566	
		Hertogs, Kurt, et al. A Rapid Method for Simultaneous Detection of Pheotypic Resistance to Inhibitors of Protease and Reverse Transcriptase in Recombinant Human Immunodeficiency Virus Type 1 Isolates from Patients Treated with Antiretroviral Drugs. Antimicrobial Agents ad Chemotherapy, February 1998, pp. 269-276	
		Ibanex, Angela, et al. Human Immunodeficiency Virus Type 1 Population Bottleneck During Indinavir Therapy Causes a Genetic Drift in the env quasispecies.. Journal of General Virology, 2000, p. 85-95	
		Konig, Herbert, et al. Azidothymidine Triphosphate Is an Inhibitor of Both Human Immunodeficiency Virus Type 1 Reverse Transcriptase and DNA Polymerase Gamma. Antimicrobial Agents and Chemotherapy, December 1989, pp. 2109-2114	
		Larder, Brendan A., et al. Zidovudine Resistance Predicted by Direct Detection of Mutations in DNA from HIV-infected Lymphocytes. AIDS, 1991, 5:137-144	
		Larder, Brendan A., et al. HIV with a Reduced Sensitivity to Zidovudine (AZT) Isolated During Prolonged Therapy. Reports, March 31, 1980, pp. 1731-1734	
		Lennerstrand, J., et al. A Method for Combined Immunoaffinity Purification and Assay of HIV-1 Reverse Transcriptase Activity Useful for Crude Samples. Analytical Biochemistry 235, 1996, pp.141-152	

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 3

Application Number	10/518,525
Filing Date	12/22/2004
First Named Inventor	Hendrika
Group Art Unit	<del>4013</del> 1648
Examiner Name	Whaley, P. Humphrey, J.
Attorney Docket Number	TIP0016US

LH	Matayoshi, Edmund D., et al. Novel Fluorogenic Substrates for Assaying Retroviral Proteases by Resonance Energy Transfer. Science, Vol. 247, pp. 954-958	
	Miller, Veronica, et al. Patterns of Resistance and Cross-Resistance to Human Immunodeficiency Virus type 1 Reverse Transcriptase Inhibitors in Patients Treated with the Nucleoside Reverse Transcriptase Inhibitor Zalcitabine. Antimicrobial Agents and Chemotherapy, December 1998, pp. 3123-3129	
	Rusconi, Stefano, et al. Susceptibility to PNU-140690 (Tipranavir) of Human Immunodeficiency Virus Type 1 Isolates Derived from Patients with Multidrug Resistance to Other Protease Inhibitors. Antimicrobial Agents and Chemotherapy, May 2000, pp. 1328-1332	
	Stuyver, Lieven, et al. Line Probe Assay for Rapid Detection of Drug-Selected Mutations in the Human Immunodeficiency Virus Type 1 Reverse Transcriptase Gene. Antimicrobial Agents and Chemotherapy, Feb. 1997, pp. 284-291	
	Toth, Mihaly V., et al. A Simple, Continuous Fluorometric Assay for HIV Protease. Int. J. Peptide Protein Res. 36, 1990, pp. 544-550	
	Tyagi, Suresh C., et al. Continuous Assay of the Hydrolytic Activity of Human Immunodeficiency Virus-1 Protease. Analytical Biochemistry 200, pp. 143-145 (1992)	
	Tyagi, Sanjay, et al. Multicolor Molecular Beacons for Allele Discrimination. Nature Biotechnology, January 1998, Volume 16, pp. 49-53	
	Vasudevachari, M.B., et al. Emergence of Protease Inhibitor Resistance Mutations in Human Immunodeficiency Virus Type 1 Isolates from Patients and Rapid Screening Procedure for Their Detection. Antimicrobial Agents and Chemotherapy, November 1996, pp. 2535-2541, Vol. 40, No. 11	
	Vergne, Laurence, et al. Genetic Diversity of Protease and Reverse Transcriptase Sequences in Non-Subtype-B Human Immunodeficiency Virus Type 1 Strains: Evidence of Many Minor Drug Resistance Mutations in Treatment-Naïve Patients. Journal of Clinical Microbiology, November 2000, p. 3919-3925, Vol. 38, No. 11	
↓	Wang, Gary T., et al. Design and Synthesis of New Fluorogenic HIV Protease Substrates Based on Resonance Energy Transfer. Tetrahedron Letters, Vol. 31, p. 6496-6496	

Examiner Signature	/Louise Humphrey/	Date Considered	01/23/2007
--------------------	-------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



SUBMISSION UNDER MPEP 609 D

Page 1 of 1

Application Number	10/518,525
Filing Date	12/22/2004
First Named Inventor	Hendrika
Group Art Unit	<del>1019</del> 1648
Examiner Name	<del>Whitney</del> Humphrey, L
Attorney Docket Number	TIP 0016US

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Name of Patentee or Applicant of Cited Document	U.S. Patent Document		Pages, Columns, Lines, where relevant passages or relevant figures appear
			Number	Kind Code <sup>2</sup> (if known)	

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Name of Patentee or Applicant of Cited Document	Foreign Patent Document			Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>2</sup>
			Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>		

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
LH		PCT Search Report dated January 4, 2005, International Application No. PCT/EP 03/50280	
LH		PCT Search Report dated November 10, 2003, International Application No. PCT/EP 03/50277	
LH		Patent Application USSN 10/519,035 filed December 22, 2004 ((Docket No. TIP 0014 US)	
LH		Patent Application USSN 10/519,436 filed December 22, 2004 (Docket No. TIP-0015 US)	

Examiner Signature	/Louise Humphrey/	Date Considered	01/23/2007
--------------------	-------------------	-----------------	------------